

REMARKS

This is a full and timely response to the non-final Official Action mailed December 15, 2004. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

By the foregoing amendment, claims 1, 11, 31, and 32 have been amended. Additionally, new claims 33-46 have been added. No claims are cancelled by the foregoing amendment. Claims 2, 12, 13, and 22-24 were cancelled previously. Thus, claims 1, 3-11, 14-21, and 25-46 are currently pending for the Examiner's consideration.

In the outstanding Office Action, claims 20 and 21 were not rejected or objected to by the Examiner. Thus, Applicant assumes that claims 20 and 21 are presently in condition for allowance.

In the outstanding Office Action, claims 1, 3, 5-9, 11-14, 16-18, 24-29, 31, and 32 were rejected as anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,393,323 to Sawan et al. ("Sawan"). Claims 4, 10, 15, 19, and 30 were rejected as unpatentable under 35 U.S.C. § 103(a) in view of the teachings of Sawan taken alone. For at least the following reasons, these rejections are respectfully traversed.

Claim 1 recites:

A method for treating a patient with urgency, frequency, urinary incontinence, and/or fecal incontinence comprising:

- providing at least one stimulator having at least two electrodes;
- implanting the at least one stimulator adjacent to at least one parasympathetic target that innervates at least one urinary, gastrointestinal, and/or other pelvic structure;
- providing operating power to the at least one stimulator;
- providing stimulation parameters to the at least one stimulator;
- generating inhibitory stimulation pulses in accordance with the stimulation parameters; and

delivering the inhibitory stimulation pulses to nerves and tissue adjacent to the at least two electrodes to inhibit parasympathetic input to said urinary, gastrointestinal, and/or other pelvic structure in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence;

wherein the stimulator has a size and shape suitable for placement adjacent to the at least one parasympathetic target.  
(emphasis added).

Claims 11, 31, and 32 recite similar subject matter.

As described in the present specification, parasympathetic input to a urinary, gastrointestinal, and/or other pelvic structure is responsible for initiating and sustaining urination and/or defecation. Hence, in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence, the claimed stimulator delivers inhibitory pulses to a parasympathetic target in order to *inhibit the parasympathetic input* to a patient's urinary, gastrointestinal, and/or other pelvic structure. Such inhibition of parasympathetic input prevents unwanted or unintentional urination and/or defecation by the patient.

In contrast, Sawan fails to teach or suggest delivering inhibitory stimulation pulses to a parasympathetic target to inhibit parasympathetic input to a patient's urinary, gastrointestinal, and/or other pelvic structure in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence. Rather, Sawan teaches a method of generating and delivering a voiding signal and a tonicity signal to the bladder to achieve bladder voiding without dyssynergia. The voiding signal is used to *activate* the bladder voiding process. As described in column 5, lines 45-55 of Sawan, the voiding signal includes a first waveform of a low frequency and high amplitude, and a second waveform of a high frequency and low amplitude. The first waveform *activates* detrusor muscle contraction. The second waveform is *only* used to inhibit contraction of the external urethral sphincter so that bladder voiding

may be induced. The second waveform is *not* used to inhibit parasympathetic input to treat urgency, frequency, urinary incontinence, and/or fecal incontinence.

Furthermore, the tonic signal prevents bladder hyperreflexia by maintaining the tonic of the pelvic floor muscle of the bladder and “slowing down contractions of the detrusor muscle which normally occurs in absence of feedback stimulation from the brain.” (Sawan, column 7, lines 10-13). The tonic signal does *not* include inhibitory pulses. Rather, the tonic signal only includes low frequency pulses. (Sawan, column 5, lines 18-19).

Thus, Sawan fails to teach or suggest using a stimulator having at least two electrodes to deliver “inhibitory stimulation pulses to nerves and tissue adjacent to the at least two electrodes to inhibit parasympathetic input to said urinary, gastrointestinal, and/or other pelvic structure in order to treat urgency, frequency, urinary incontinence, and/or fecal incontinence.” “A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). *See* M.P.E.P. § 2131. Because Sawan fails to teach or suggest all the features of claims 1, 11, 31, and 32, the rejection of these claims and their respective dependent claims based on Sawan should be reconsidered and withdrawn.

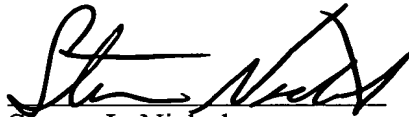
Newly added claims 33-46 recite methods and systems for treating a patient with a bowel dysfunction and are fully supported by the present application as originally filed. Sawan does *not* teach or suggest a method or system of treating a patient with a *bowel* dysfunction as recited in the newly added claims. Rather, Sawan only teaches a method of

generating and delivering a tonicity signal and a voiding signal to the *bladder*. Therefore, the newly added claims should be considered and allowed.

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper which have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: 7 March 2005

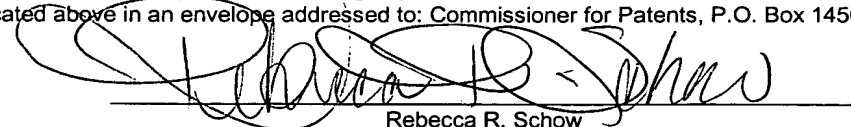
  
Steven L. Nichols  
Registration No. 40,326

Steven L. Nichols, Esq.  
Managing Partner, Utah Office  
**Rader Fishman & Grauer PLLC**  
River Park Corporate Center One  
10653 S. River Front Parkway, Suite 150  
South Jordan, Utah 84095  
(801) 572-8066  
(801) 572-7666 (fax)

**CERTIFICATE OF MAILING**

DATE OF DEPOSIT: March 7, 2005

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail on the date indicated above in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Rebecca R. Schow